Applicants: Emmanuel Delorme, et al. Attorney Docket No.: 2003456-US

Serial No.: 10 / 811,158 Filed: 29 March, 2004

Page: 7 of 12

Remarks

In the above-referenced final Office Action, pending claims 22, 36-39, 41, and 42 were rejected.

Applicants respectfully request entry of this reply, and reconsideration and allowance of claims 22, 36-39, 41, and 42, and also new claims 43 and 44, pursuant to 37 CFR §1.116. Applicants also respectfully request withdrawal of the finality of the above referenced Action pursuant to MPEP §706.07(e).

Previously submitted Information Disclosure Statement.

Applicants gratefully acknowledge that the Examiner has now considered each reference presented in a three-page supplemental <u>Information Disclosure Statement By Applicant</u> of 12 March, 2008.

Drawings.

Applicants note that in their <u>Amendment and Reply</u> of 02 May, 2008, one replacement sheet of drawings, including figures 13 and 14, was entered in response to certain objections to the drawings stated in a previous Action herein of 11 February, 2008.

Claim Rejections - 35 U.S.C. §112.

In the above referenced Action, claims 38 and 39 were rejected under §112 as allegedly being indefinite. Claim 38 had recited a limitation of "the upper and lower stabilizers" that, allegedly, had insufficient antecedent basis "because the lower stabilizers have not been previously claimed." Claim 39 depends on claim 38 and was thus similarly rejected.

Attorney Docket No.: 2003456-US Applicants: Emmanuel Delorme, et al.

Serial No.: 10 / 811,158 29 March, 2004

Filed: Page:

8 of 12

In response, claim 38 has been amended herein to address the rejection and is therefore believed to be allowable; and dependent claim 39 is therefore believed to be allowable as well.

Claim Rejections - 35 U.S.C. §103.

In the above referenced Action, claims 22, 36-39, 41, and 42 were rejected under §103(a) as allegedly being unpatentable over Jacquetin (US 7,131,944) in view of Gellman (WO 98/35632).

In response, Applicants traverse the Examiner's rejections and respectfully renew their arguments made in their response of 02 May, 2008.

Re claim 22.

The Examiner alleges that Jacquetin discloses all features of claim 22 except for "at least two orifices", but that Gellman discloses "two orifices" in an implant body. Applicants traverse this rejection.

Claim 22 requires two upper suspension stabilizers and two lower suspension stabilizers. The Examiner refers to an implant shown in Figure 10 and alleges that the device meets Applicants' claim limitations except for two orifices. However, Figure 10 is solely directed to an anterior implant (e.g., column 2, lines 37-39) for treatment of cystocele. Jacquetin teaches a clear distinction between anterior and posterior implants, for treatment of cystocele and rectocele, respectively, at column 1, lines 53-67, through column 2, lines 1-11. For treatment of rectocele, Jacquetin only discloses a posterior implant having a tape portion (56) with a single pair of straps (see, e.g., column 4, lines 15-35; and column 4, lines 52-56). Notably, Applicants in fact teach that devices having only a support body and two suspension cords - being structurally analogous to Jacquetin's two-strap posterior implant - are inadequate for use as posterior implants due to their instability among other disadvantages in treatment of rectocele. See, e.g., Applicant's specification at page 1, lines 21-34. Likewise, Applicants also note that Jacquetin's four-strap anterior implant is exclusively configured to repair a cystocele through specified design parameters of the body of the anterior implant (see, e.g., Figure 1 and column 3,

Applicants: Emmanuel Delorme, et al. Attorney Docket No.: 2003456-US

Serial No.: 10 / 811,158 Filed: 29 March, 2004

Page: 9 of 12

lines 56-67). Thus, Applicants assert that Jacquetin is wholly inapplicable to a determination of patentability of the rectocele implant of claim 22.

Regarding the Examiner's combination of Jacquetin with Gellman in rejecting claim 22, Gellman discloses simple slings for treating urinary incontinence, which would not be suitable for treating rectocele as aforementioned. Gellman's slings have suture receiving sites or apertures (18) that, in some embodiments, are provided with a reinforcing device to minimize a possibility of tearing the sling from interaction with sutures passing through the sites. See, e.g., Figures 5C-5F; page 10, lines 13-21; page 11, lines 10-18; page 17, lines 23-25; and page 18, lines 6-14. Nowhere does Gellman teach or even suggest placement of anything other than sutures through the sites (18). Applicants respectfully assert that the Examiner has not pointed out any teaching, suggestion, or motivation to combine Jacquetin and Gellman. Jacquetin only teaches a two-armed posterior implant, while Gellman only teaches a suburethral sling having suture receiving sites. Neither Jacquetin nor Gellman, alone or in combination, teach or even suggest the support body, pairs of upper and lower suspension stabilizers, and orifices in the support body for receiving stabilizers, of claim 22. In sum in the present Action, the Examiner has simply identified a reference illustrating a two-strap implant and an unrelated reference illustrating "suture receiving sites", and arbitrarily combined them without motivation or support. The Examiner has failed to point out any teaching, suggestion, or motivation that one of ordinary skill in the art would have combined suture receiving sites in an incontinence sling with an implant for treatment of prolapse having at least four stabilizers. The pending claim is thus clearly distinguishable over the art of record.

Applicants therefore respectfully assert that claim 22 is not obvious under Jacquetin combined with Gellman, since neither reference teaches or suggests, either alone or in combination, a posterior implant for treatment of rectocele with four or more stabilizers and at least two orifices. But, for the sake of expediency in prosecution, the claim has been amended herein to be explicitly directed to treatment of rectocele. Therefore, Applicants believe that this claim is allowable and respectfully request withdrawal of the rejection.

Applicants: Emmanuel Delorme, et al. Attorney Docket No.: 2003456-US

Filed:

Serial No.: 10 / 811,158 29 March, 2004

Page:

10 of 12

Re claims 36-39.

The Examiner alleges that Jacquetin discloses all features of method claims 36-39, as stated relative to claim 22, except for their various other features.

The Examiner alleges that claims 36 and 37 are obvious because "Jacquetin in column 3 lines 9 and 10 discloses the implant can be modified by the surgeon to accommodate different patients." However, it is clear that any modifications under the teachings of Jacquetin would only be with respect to sizing and scale for fitting a particular patient's anatomy, since posterior implants for treating rectocele are solely shown and described with respect to Jacquetin's figures 2 and 11 as implants having only two straps. Jacquetin's other variations are shown and described only as anterior implants for treating cystocele. These pending claims are thus not obvious over the art of record.

The Examiner also alleges that claim 38 is obvious "because Jacquetin discloses that the extra arms are simply for increasing lateral support (column 9, lines 30-35) it appears as though the device would perform equally well with additional middle stabilizers." However, Applicants again respectfully point out that the Examiner seems to have again confused Jacquetin's anterior implant for treatment of cystocele with Jacquetin's posterior implant for treatment of rectocele. The teaching of column 9, lines 30-35, is only in the context of figure 10 which is an anterior implant for treatment of cystocele. Thus, this teaching is inapplicable to pending claim 38 that is directed to treatment of rectocele. Also regarding claim 38, the Examiner again alleges that "Jacquetin's implant can be modified by the surgeon to accommodate different patients." As aforementioned, however, any modifications under the teachings of Jacquetin would only be with respect to sizing and scale of an implant with two straps. This pending claim is thus not obvious over the art of record.

The Examiner additionally alleges that claim 39 is obvious because "Gellman teaches posterior stabilizers of an anterior prosthesis as sutures that is received by orifices (18) on the body (see col.7 line 19). These sutures passing through the orifices (18) at the upper portion of the implant allow support the upper portion of the implant. Sutures of Gellman are acting as the posterior stabilizers of an anterior prosthesis." As best understood, this allegation again appears to substitute Gellman's suture receiving sites for orifices recited in the claim when there is

Applicants: Emmanuel Delorme, et al. Attorney Docket No.: 2003456-US

Serial No.: 10 / 811,158 Filed: 29 March, 2004

Page: 11 of 12

provided no teaching, suggestion, or motivation to do so. Therefore, Gellman is inapplicable to pending claim 39 and thus it is not obvious over the art of record.

Applicants therefore traverse the rejections of claims 36-39. But, for the sake of expediency in prosecution, they have been amended herein to be explicitly directed to treatment of rectocele. Thus, Applicants believe that these claims are allowable and respectfully request withdrawal of the rejections.

Re claims 41 and 42.

Lastly, the Examiner alleges that apparatus claims 41 and 42 are obvious because, *inter alia*, "Jacquetin/Gellman teaches the claimed invention as applied for claim 22." However, as stated above, Applicants assert that neither Jacquetin nor Gellman, alone or in combination, render these claims obvious.

Applicants therefore traverse the rejections of claims 41 and 42. But, for the sake of expediency in prosecution, they have been amended herein to be explicitly directed to treatment of rectocele. Thus, Applicants believe that these claims are allowable and respectfully request withdrawal of the rejections.

New claims.

Applicants have presented new claims 43 and 44 herein that are believed to be adequately and fully supported by the specification, and with regard to which no new matter has been introduced. Similarly to claims 22, 36-39, 41, and 42, these new claims 43 and 44 are also believed to be allowable in light of the foregoing observations.

* * *

Attorney Docket No.: 2003456-US Applicants: Emmanuel Delorme, et al.

Serial No.: 10 / 811,158

Filed: Page: 29 March, 2004 12 of 12

CONCLUSION

Claims 22, 36-39, 41, and 42 have been amended herein. Claims 43 and 44 are new.

Applicants submit that claims 22, 36-39, and 41-44 are in condition for allowance, which action is respectfully requested.

Accompanying this reply is a separate Patent Application Fee Determination Record document. A fee pertaining thereto will be paid via deposit account and the EFS-Web system upon submission hereof; and the Director is hereby authorized to charge deposit account no. 50-4439 if any additional fee is required.

The Examiner is invited to telephone the undersigned counsel, if such conversation would further prosecution.

> Respectfully submitted, Emmanuel Delorme, et al.

Dated: 05 February, 2009

Signed:

Walter K. (Kevin) Roloff, Reg. No. 36,907

U.S. Patent Counsel

Coloplast Corp., Coloplast A/S

W. R. Roloff

Customer No. 69289

Telephone: (612) 302-4974